II. 510(k) SUMMARY

AUG 2 3 2002

A. Sponsor/Submitter:

Perclose
400 Saginaw Drive
Redwood City, CA 94063
Tel: (650) 474-3000
Fax: (650) 474-3020

B. Contact Person:

Sevrina Ciucci
Regulatory Affairs Coordinator
(650) 474-3164

C. Date of Submission: July 9, 2002

D. Trade (Brand) Name: Chito-Seal™

E. Common Name: Topical Hemostasis Pad

F. Classification: Unclassified Device

G. Classification Name: Dressing

H. Product Code: 79FRO

I. Predicate Device: Marine Polymer Technologies SyvekPatch® (K984177)

J. Intended Use:

Chito-Seal is indicated for use in the management of bleeding wounds such as vascular access sites and percutaneous catheters or tubes. Chito-Seal promotes the rapid control of bleeding in patients on hemodialysis and in patients on anticoagulation therapy.

K. Device Description:

Chito-Seal is a topical bandage intended to promote hemostasis when in contact with a bleeding wound.

L. Summary of Substantial Equivalence:

Perclose has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that Chito-Seal is substantially equivalent to currently marketed predicate device.

Chito-Seal has essentially the same intended use as the predicate device. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing was conducted. Animal testing was performed to simulate clinical conditions with no adverse effects noted. Clinical evidence further supported the safety and performance of Chito-Seal.

In conclusion, Chito-Seal has been shown to be substantially equivalent to the Class I predicate on which the device is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2002

Ms. Sevrina Ciucci
Regulatory Affairs Coordinator
Perclose
400 Saginaw Drive
Redwood City, California 94063

Re: K021062
Trade/Device Name: Chito-Seal™
Product Code: FRO
Dated: July 9, 2002
Received: July 11, 2002

Dear Ms. Ciucci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VII. STATEMENT OF INDICATIONS FOR USE

510(k) Number: K021062

Device Name: Chito-Seal™

Indications for Use: Chito-Seal is indicated for use in the management of bleeding wounds such as vascular access sites and percutaneous catheters or tubes. Chito-Seal promotes the rapid control of bleeding in patients on hemodialysis and in patients on anticoagulation therapy.

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021062